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Magnitude and variability of loading on the osseointegrated implant of transfemoral amputees during walking

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Abstract
This study directly measured the load acting on the abutment of the osseointegrated implant system of transfemoral amputees during level walking, and studied the variability of the load within and among amputees. Twelve active transfemoral amputees (age: 54±12 years, mass:84.3±16.3 kg, height: 17.8±0.10 m) fitted with an osseointegrated implant for over 1 year participated in the study. The load applied on the abutment was measured during unimpeded, level walking in a straight line using a commercial six-channel transducer mounted between the abutment and the prosthetic knee. The pattern and the magnitude of the three-dimensional forces and moments were revealed. Results showed a low step-to-step variability of each subject, but a high subject-to-subject variability in local extrema of body-weight normalized forces and moments and impulse data. The high subject-to-subject variability suggests that the mechanical design of the implant system should be customized for each individual, or that a fit-all design should take into consideration the highest values of load within a broad range of amputees. It also suggests specific loading regime in rehabilitation training are necessary for a given subject. Thus the loading magnitude and variability demonstrated should be useful in designing an osseointegrated implant system better able to resist mechanical failure and in refining the rehabilitation protocol.

Keywords:
Transfemoral amputation; Prosthetics; Osseointegration; Transducer; Gait; Variability

1. Introduction

A lower-limb prosthesis is conventionally suspended to the residual limb by a socket. Problems in terms of residual limb pain and soft tissue breakdown from the prosthetic socket have been described to be common [1–3]. Recent developments in innovative surgical approaches for directly connecting a prosthesis into the femur using a titanium implant (osseointegration) might help alleviate these problems [4,5]. One of the most advanced implant systems currently available includes a titanium implant and an abutment [4]. The proximal end of the abutment is attached to the implant while its distal end protrudes through the soft tissue allowing attachment of the external prosthesis, as shown in Fig. 1. The absence of the prosthetic socket can alleviate the skin problems and residual limb pain [6]. In addition, amputees can enjoy a greater hip range of motion and better sitting comfort [7], as well as be more active [6,9] than they can with socket-type prostheses. They also experience improved sensory feedback, referred as osseoperception [4]. External components of the prosthesis can be attached to and detached from the abutment easily. There are currently over 80 transfemoral amputees in the world fitted with this osseointegrated implant developed by Dr. R. Branemark [4].

However, mechanical failures of the abutment as well as the lengthy rehabilitation program are the potential drawbacks of this surgical approach [6,8,9]. Mechanical failure of the abutment occurred due to a permanent deformation following a fall of the amputee [6] or a fatigue failure after extensive use. The ability for the abutment to bend protects the bone from overload. An increased understanding on the load developed during walking will help optimize the strength of the abutment and develop devices to protect the implant system. The rehabilitation program is started after the surgical insertion of the abutment [10]. One important rehabilitation exercise is to apply incremental static load on the implant system using a conventional weigh-scale as a force transducer. The aim of the weight-bearing exercise is to prepare the bone to tolerate forces transmitted by the implant when the amputees are walking. Walking exercise with assistive devices is proceeded after the residual limb can bear full body weight safely without the perception of severe pain. Usually it requires a minimum of 4–6 months of weight-bearing and walking exercises prior to achieving gait without any assistive devices Understanding the load experienced during walking might help refine the loading protocol of the weight bearing exercise to prepare the amputees for earlier independent walking. In addition, loosening of implants after long-term usage might be a potential issue due to the load transfer from the bone to the implant (stress shielding), but there are no data yet available in the literature indicating the occurrence of aseptic loosening.

Mechanical failures of the abutment, the loading protocol of rehabilitation exercises, and the potential problem of implant loosening are all related to mechanical loading. Hence, understanding the load applied on the abutment is an important step to solve these problems. Conventionally, the load can be calculated using inverse dynamics relying on the motion of the prosthesis captured by a motion analysis system and the ground reaction forces measured by a force plate [11,12]. The drawbacks of this method are that only one or two steps of walking are usually measured, force-plate targeting can produce altered gait [13], accurate determination of the inertia of the limb segments are needed, and errors could be compounded when involving more than one joint above the ankle. Direct load measurement can ease some of these problems. Previous studies have used load transducers to measure directly the forces and moments applied at the distal end of the residuum (socket or implant) during unlimited number of steps [14–17]. However, they included no more than two participants. Load data on larger number of amputees using osseointegrated implants are needed to better understand the variability within and among participants. The loading magnitude and variability will be useful in the evaluation and design of the implant system as well as the refinement of the rehabilitation protocol.

This study aimed to present:

(A) The measurement of the load applied on the osseointegrated implant system of transfemoral amputees during normal walking in a straight line.

(B) The step-to-step and subject-to-subject variability of the load for a group of 12 transfemoral amputees.

2. Methods

2.1. Participants

A total of three female and nine male unilateral trans-femoral amputees representing approximately 15% of the current global population of amputees fitted with osseointegrated implants, participated in this study. The demographic details of each subject are summarized in Table 1.

All participants have been walking with the implant for at least 1 year. They could walk 200 m independently without additional walking aids. The body mass of the participants should be below 110 kg to avoid reaching the maximum capacity of the load transducer (1140 N). Load measurement took place in a clinical environment in the Caulfield General Medical Centre, Melbourne, Australia (subjects 1 and 2), and Sahlgrenska University Hospital, Gothenburg, Sweden (subjects 3–12). Human research ethical approval was received from the Queensland University of Technology. Written consent was obtained from all participants.

2.2. Apparatus

The technique used to directly measure the load is similar to the one described in a previous study [16]. A six-channel load transducer (Model 45E15A; JR3 Inc., Woodland, CA) was used to directly measure the forces and moments applied on the abutment. The 762 g transducer was power supplied by a customized battery pack placed in a waist pack. Data are processed using a calibration matrix, provided by JR3 Inc., Woodland, CA, to eliminate cross-talk between axial sensors. A previous experiment demonstrated that forces and moments along the three axes were measured by the transducer with an error of less than ±1 N and ±1Nm [16], respectively. The transducer was mounted to customized plates that were positioned between the abutment or the Rotasafe and the knee. Rotasafe is a device based on a safety clutch or ratchet that triggers when the torsional load on the long axis of the femur exceeds a setup threshold in order to prevent excessive torque on the abutment. The transducer was aligned so that its vertical axis was co-axial with the long axis (compression was positive) of the abutment. The other axes corresponded to the anatomical antero-posterior (anterior was positive) and medio-lateral direction (lateral was positive) of the abutment as depicted in Fig. 2. A wireless transmitter (Ricochet Model 21062; Metricom Inc., Los Gatos, CA) was used to transmit data from the transducer to a nearby receiver connected to a laptop computer. The 200 g transmitter was connected to the transducer via a serial cable and placed in the waist pack. Each channel was sampled at 200 Hz.

Amputees were fitted with their usual prosthetic components. Different types of prosthetic knees, prosthetic feet, and footwear were used, as presented in Table 1. The adaptor usually connecting the Rotasafe (torque protection device) to the knee joint was removed and the empty space was substituted by the load transducer. Using the Rotasafe was recommended for all the participants. However, a compromise was made for five participants who walked without the Rotosafe due to the lack of space to fit the load transducer. The transducer was fitted by a prosthetist who replicated the usual alignment of the prosthesis for each amputee. Using the currently used prosthesis (components and alignment) allowed an assessment of the true variability among participants taking into consideration the full extent of prostheses setup differences.

2.3. Protocol

Approximately 15 min of practice with the instrumented prosthetic leg was allowed before load measurement to ensure subject confidence, safety and comfort. Then, the participants were asked to perform two trials of walking along the 60 m walkway located in Sahlgrenska University Hospital, or six trials along the 20 m walkway located in the Caulfield General Medical Centre. Subject 2 performed only one trial due to physical constraints. The amputees were required to walk at self-selected comfortable walking speed. The total number of walking steps for each amputee, presented in Table 1, varied depending upon the stride length. Sufficient rest was given between walking trials to avoid fatigue. Finally, the prosthesis was detached from the residuum to enable a 1 min recording without load applied on the transducer for calibration purposes.

2.4. Data analysis

The raw force and moment data were imported and processed by a customized Matlab software program (Math Works, Inc.). The initial data reduction included the following steps:

- Step 1: Calibration. Raw force and moment data were calibrated using a specific recording of the initial, unloaded conditions to remove any offset in the data and a transducer specific calibration matrix is applied to eliminate sensor cross-talk.
- Step 2: Selection of relevant segment of data to analyse. The first and the last strides recorded for each trial were discarded in order to ensure that the analysis only included the data obtained when the subject walked at a uniform pace.
- Step 3: Determination of gait events. The curve of the vertical force was used to manually detect the heel contact and toe-off with a demonstrated accuracy of ±0.01 s. This accuracy was determined in a preliminary study where the detection of gait events using the method above was compared to force-plate data collected simultaneously [15].

The three dimensional forces and moments of each gait cycle of the prosthetic leg were analysed using conventional parameters:

- Patterns of curves. The forces and moments produced during each gait cycle was normalized to 100%, so that the force and moment curves can be plotted with the same time scale.
- Local extrema. The time of occurrence (expressed in percentage of the stance phase time) and the magnitude of local peaks and valleys of the body-weight normalized forces and moments, occurring in circled areas presented in Figs. 3 and 4, respectively, were determined for each step of the prosthetic limb.
- Impulse values. The conventional trapezoid method was used to integrate the area under the force–time curves normalized by the body weight (FAP, FML, and FL) to provide the impulse (IAP, IML and IL) for each step of the prosthetic limb.

The means and standard deviations (S.D.) of the local extrema (time of occurrence and magnitude) and of the impulse were calculated. The step-to-step variability of each subject and subject-to-subject variability were also assessed using the coefficient of variance (COV), which is defined as the standard deviation (S.D.) divided by the mean modulus.

3. Results

3.1. Patterns of forces and moments

The forces and moments applied on the antero-posterior (FAP, MAP), medio-lateral (FML, MML) and long axes (FL, ML) for a gait cycle of each subject are plotted in Figs. 3 and 4. Each curve represents the mean of all the steps measured for each subject (N = 12). The three components of forces followed a pattern that was similar to the ground reaction forces obtained with force-plates [18]. As expected, forces applied on the long axis (FL) were the largest in magnitude among the three components of forces and presented two peaks. The abutment experienced some braking posterior forces (negative FAP) during early stance phase and propulsive anterior forces (positive FAP) during the late stance phase of the gait. The abutment consistently experienced some lateral forces (FML) during stance phase of the gait. The forces and moments did not fall to zero during the swing phase. This is so because the mass of the prosthesis located below the transducer is being pulled away from the transducer due to gravity and due to centrifugal forces while rotating around the prosthetic knee and anatomic hip.

A lateral rotational moment (MAP) was consistently experienced during stance phase of the gait. Three participants produced posterior rotational moments (MML) throughout the entire gait cycles. All other participants demonstrated some anterior rotational moments peaking at about 40% of the gait, and posterior rotational moments peaking at about 60% of the gait when the prosthetic feet prepared to leave the ground. The variations in the patterns of MML could suggest that different strategies were used in controlling the prosthetic knee joints. Axial rotational moment (ML) was the lowest in magnitude compared to MAP and MML because of the shorter moment arm. Inconsistent ML patterns were shown among participants including internal and external rotation over the stance phase.

3.2. Local extrema

A total of eight local extrema were studied, which represented the key features of the curve plotting forces and moments against time as presented in Figs. 3 and 4, respectively. Two local extrema were identified for FAP for the maximum anterior and posterior forces, one for FML for the maximum lateral force, and two local extrema for FL concerning the two peaks. One local extremum was located for MAP for the maximum lateral rotational moment, and two for MML for the maximum anterior and posterior rotational moment. No local extremum was identified for ML because of the high inconsistencies among subjects.

The statistical results including the coefficient of variance (COV) of the time of occurrence and magnitude of local extrema for the forces and moments within and across participants are shown in Tables 2 and 3, respectively. It can be observed that the COV for each subject was small. In most cases, it was lower than 0.15. However, the COV calculated among participants was larger with a maximum of 1.18. A smaller COV was seen in the body-weight normalized long axis forces (FL1 and FL2) than forces in the other two axes (FAP1, FAP2 and FML).

3.3. Impulse

The overall loading of the prosthesis over the support phase represented by the impulse is provided in Table 4.As expected, the impulse regarding the long axis (IL) was the largest in magnitude among the three axes. The COV within subjects was small which ranged between 0.03 and 0.17. The COV was quite large among participants ranging between 0.11 and 0.57.

4. Discussion

This study used a portable recording system based on a load transducer and a wireless modem. This allowed direct measurement of the load applied on the abutment. Direct measurement could allow higher number of walking steps to be recorded and more accurate results, as compared to the calculation of the load using inverse dynamics. The wireless system allowed the loading to be measured when the subjects walked unimpeded. Similar measurements have been conducted when the amputees perform various activities of daily living [19].

The measured load could have certain implications in rehabilitation protocols and the designs of the implant system. The large COV across the body-weight normalized forces, moment and impulses of each subject indicates a high subject-to-subject variability. This can be explained by the broad range of anthropometric characteristics, different walking patterns and prosthetic components. The large variability implies that a specific loading regime in weight-bearing exercise might be necessary for a given subject. In current practice, amputees are initially requested to apply 20 kg of load to the abutment as measured by a weigh scale [10]. The loading is increased incrementally over a period of 6 weeks until full standing weight can be borne safely and without pain. The improved understanding of the load experienced during walking could provide further guidelines for the load magnitude prescribed to each specific amputee. The results suggest that the load experienced during walking could not be easily predicted by the body weight of the amputees alone. Further studies can investigate if there is any relationship between the load applied on the conventional socket-type prosthesis before the surgical implantation and that applied on the osseointegrated implant system of the same amputee. Studies can also be performed to investigate the effect of factors, such as age, gender and physical capabilities on the load applied on the residuum.

The large subject-to-subject variability also confirms that the mechanical design of the implant system should be customized for each individual, or that a fit-all design should take into consideration the highest values of load within a broad range of amputees. The load magnitudes can assist in determining the load inputs for structural tests and computational modelling in evaluating the structural integrity of the abutment. By applying cycles of walking load to the implant system, the fatigue life can be determined. The ability for the abutment to bend protects the bone from overload. The load data can also be useful in designing a fail-safe device to protect the abutment. When designing an implant system which accommodates various amputees, a factor of safety could be applied to ensure the load experienced during daily activities are well below the load causing mechanical failures. This accounts for the large variability among amputees and some uncertainties such as surface imperfections. The subject-tosubject variability reported in this study could aid in defining a more realistic factor of safety.

On the other hand, a small COV was found for each subject which demonstrated a low step-to-step variability of the limb fitted with osseointegrated prostheses. This suggests that measuring force for one to two walking steps using a force-plate may adequately reflect the loading pattern of a subject. This tends to validate gait laboratory-based studies using inverse dynamics based on data from force plates and motion capture systems, assuming that the placement of the reflective markers as well as the inertia and dimensions of the limb are determined accurately.

5. Conclusions

This study directly measured the load acting on the abutments of 12 transfemoral amputees fitted with osseointegrated implants during normal, unimpeded, straight, level walking. This is the first attempt at measuring the magnitude of variability of the load applied on the osseointegrated implant. Results showed a low step-to-step variability which tends to validate gait laboratory-based studies focussing on a limited number of steps. Results also demonstrated a high subject-to-subject variability in force and moment data which tends to highlight the need for individual-based rather than population-based biomechanical analyses of transfemoral amputees. This study provides essential information to biomechanists, engineers and clinicians facing the challenge of analysing the kinetics of lower-limb amputees within experimental and clinical conditions, and for the design of new generation of osseointegrated devices.

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Conflict of interest
Prof. Rickard Branemark is involved in the development and commercialization of the osseointegrated fixation used by the amputees participating in the study. However, this involvement does not interfere in any shape or form with the background, methods, results, discussion and conclusions sections of this manuscript.

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Table 1. Demographics, number of walking steps recorded and setup of the prosthesis for each subject

	Gender (M/F)	Age (years)	Height (m)	Total mass (kg)	No. of gait cycle	Side of amputation (L/R)	Footwear	Foot	Knee	Rotosafe
Subject 1	F	39	1.71	68	43	R	Running shoes	Multiflex	Total knee	No
Subject 2	M	46	1.82	96.1	24	L	Running shoes	Multiflex	Total knee	No
Subject 3	F	57	1.63	61.1	34	R	Sandals	Total concept	Total knee	Yes
Subject 4	M	50	1.81	74.3	59	L	Sandals	TruStep	Total knee	No
Subject 5	M	59	1.89	87.1	48	R	Leather shoes	TruStep	Total knee	No
Subject 6	M	62	1.8	105	64	L	Running shoes	Mercury	Blachford's	Yes
Subject 7	F	49	1.58	53.3	59	R	Sandals	Total concept	Total knee	Yes
Subject 8	M	41	1.77	96.6	62	R	Running shoes	C-Walk	Total knee	No
Subject 9	M	26	1.78	90	53	R	Leather shoes	Carbon Copy	C-leg	Yes
Subject 10	M	46	1.99	99.5	56	L	Sandals	C-Walk	Total knee	Yes
Subject 11	M	50	1.82	99.8	54	R	Leather shoes	Flex foot	GaitMaster	Yes
Subject 12	M	45	1.72	80.4	61	R	Running shoes	TruStep	Total knee	Yes
Mean		48	1.78	84.3	51					
S.D.		9.7	0.1	16.8	12					
COV		0.204	0.056	0.199	0.235					
Maximum		62	1.99	105	64					
Minimum		26	1.58	53.3	24					
Range		36	0.41	51.7	40					

The total mass includes body mass plus the mass of the instrumented prosthesis.

Table 2. Step-to-step and subject-to-subject variability of the time of occurrence (expressed in percentage of the stance phase time) and of the magnitude (expressed in percentage of body weight) of local extrema of the force along the antero-posterior (FAP1, FAP2), medio-lateral (FML), and long axis (FL1, FL2)

	F_{AP1}		F_{AP2}		F_{ML}		F_{L1}		F_{L2}	
	Mean	COV	Mean	COV	Mean	COV	Mean	COV	Mean	COV
Time (in %SP)										
Step-to-step variability										
Subject 1	30.80	0.061	82.10	0.024	33.20	0.056	36.70	0.067	69.80	0.039
Subject 2	13.40	0.310	83.10	0.021	72.00	0.025	35.60	0.187	72.20	0.027
Subject 3	17.60	0.100	84.70	0.015	93.20	0.033	24.70	0.129	69.60	0.051
Subject 4	17.30	0.134	74.90	0.025	74.60	0.030	31.30	0.160	69.30	0.032
Subject 5	21.30	0.160	88.90	0.052	70.50	0.026	25.80	0.148	69.70	0.022
Subject 6	18.40	0.138	80.20	0.022	79.60	0.027	35.50	0.103	68.40	0.047
Subject 7	18.40	0.163	80.90	0.075	73.60	0.072	24.60	0.163	76.00	0.071
Subject 8	16.80	0.123	79.30	0.020	72.00	0.030	36.70	0.055	69.70	0.028
Subject 9	19.50	0.119	85.50	0.018	78.20	0.017	24.50	0.135	67.70	0.042
Subject 10	17.60	0.095	82.30	0.027	72.00	0.054	42.20	0.068	68.90	0.030
Subject 11	13.90	0.127	80.10	0.018	76.70	0.020	38.10	0.060	74.10	0.065
Subject 12	8.90	0.174	76.80	0.039	67.80	0.130	41.20	0.128	68.80	0.082
Subject-to-subject variability										
Mean	17.80	0.142	81.57	0.030	71.95	0.043	33.08	0.117	70.35	0.045
S.D.	5.22	0.062	3.80	0.018	13.82	0.032	6.64	0.045	2.48	0.019
COV	0.293	0.434	0.047	0.594	0.192	0.737	0.201	0.388	0.035	0.430
Maximum	30.80	0.310	88.90	0.075	93.20	0.130	42.20	0.187	76.00	0.082
Minimum	8.90	0.061	74.90	0.015	33.20	0.017	24.50	0.055	67.70	0.022
Range	21.90	0.249	14.00	0.060	60.00	0.113	17.70	0.132	8.30	0.060
Magnitude (in %BW)										
Step-to-step variability										
Subject 1	−5.07	0.108	10.80	0.096	10.80	0.070	105.00	0.018	97.20	0.023
Subject 2	−9.82	0.128	14.50	0.043	14.10	0.056	91.80	0.040	87.90	0.025
Subject 3	−13.20	0.016	21.70	0.018	7.36	0.071	80.70	0.034	83.40	0.017
Subject 4	−5.78	0.107	14.60	0.048	8.42	0.046	87.00	0.038	94.40	0.016
Subject 5	−15.40	0.132	10.20	0.074	11.60	0.049	88.50	0.038	102.00	0.022
Subject 6	−4.22	0.141	3.22	0.100	23.60	0.112	96.50	0.032	93.70	0.024
Subject 7	−11.10	0.068	15.90	0.038	19.20	0.045	97.30	0.036	90.60	0.018
Subject 8	−5.07	0.170	13.20	0.040	11.10	0.036	83.20	0.027	86.90	0.025
Subject 9	−7.46	0.085	11.50	0.061	11.40	0.092	79.10	0.046	72.20	0.036
Subject 10	−7.41	0.101	15.20	0.030	12.40	0.117	85.20	0.033	84.30	0.024
Subject 11	−5.46	0.119	21.50	0.020	15.30	0.068	89.60	0.029	81.40	0.048
Subject 12	−4.90	0.306	16.20	0.048	5.60	0.101	87.90	0.027	82.40	0.041
Subject-to-subject variability										
Mean	−7.91	0.123	14.04	0.051	12.57	0.072	89.32	0.033	88.78	0.027
S.D.	3.64	0.069	4.99	0.027	5.01	0.028	7.44	0.007	8.75	0.010
COV	0.460	0.563	0.355	0.523	0.398	0.384	0.083	0.221	0.099	0.374
Maximum	−4.22	0.306	1.31	2.306	3.31	4.306	5.31	6.306	7.31	8.306
Minimum	−15.40	0.016	3.22	0.018	5.63	0.036	79.06	0.018	72.20	0.018
Range	11.18	0.290	1.91	2.288	2.32	4.270	73.75	6.288	64.89	8.288

Table 3. Step-to-step and subject-to-subject variability of the time of occurrence (expressed in percentage of the stance phase time) and of the magnitude of local extrema of the body weight normalized moment about the antero-posterior (MAP), medio-lateral (MML1, MML2)

	M_{AP}		M_{ML1}		M_{ML2}	
	Mean	COV	Mean	COV	Mean	COV
Time (in %SP)						
Step-to-step variability						
Subject 1	71.30	0.097	75.80	0.042	93.90	0.017
Subject 2	40.70	0.106	9.90	0.112	70.20	0.019
Subject 3	25.40	0.330	69.70	0.062	91.80	0.015
Subject 4	80.60	0.033	71.90	0.025	92.50	0.015
Subject 5	25.00	0.155	68.90	0.026	90.90	0.019
Subject 6	71.30	0.029	60.80	0.103	92.60	0.013
Subject 7	26.80	0.099	54.30	0.125	90.80	0.071
Subject 8	12.70	0.144	80.50	0.108	91.70	0.020
Subject 9	25.20	0.084	70.10	0.029	89.10	0.009
Subject 10	21.80	0.219	69.00	0.127	90.70	0.029
Subject 11	32.70	0.094	71.40	0.045	95.00	0.018
Subject 12	45.70	0.111	67.40	0.052	89.00	0.018
Subject-to-subject variability						
Mean	39.90	0.125	64.14	0.071	89.85	0.022
S.D.	22.60	0.082	18.31	0.040	6.45	0.016
COV	0.566	0.658	0.286	0.567	0.072	0.738
Maximum	80.60	0.330	80.50	0.127	95.00	0.071
Minimum	12.70	0.029	9.90	0.025	70.20	0.009
Range	67.90	0.301	70.60	0.102	24.80	0.062
Magnitude (in m)						
Step-to-step variability						
Subject 1	0.017	0.225	0.007	0.434	−0.018	0.115
Subject 2	0.043	0.049	0.007	0.512	−0.033	0.110
Subject 3	0.011	0.142	0.001	1.693	−0.021	0.042
Subject 4	0.026	0.053	0.020	0.081	−0.022	0.059
Subject 5	0.035	0.065	0.008	0.307	−0.040	0.037
Subject 6	0.028	0.100	0.038	0.075	−0.006	0.466
Subject 7	0.040	0.059	−0.002	0.936	−0.022	0.058
Subject 8	0.010	0.179	−0.002	1.229	−0.018	0.121
Subject 9	0.033	0.059	−0.003	0.930	−0.031	0.049
Subject 10	0.033	0.051	0.022	0.271	−0.029	0.253
Subject 11	0.036	0.059	0.024	0.102	−0.030	0.039
Subject 12	0.023	0.085	0.027	0.118	−0.020	0.100
Subject-to-subject variability						
Mean	0.028	0.094	0.012	0.557	−0.024	0.121
S.D.	0.011	0.058	0.013	0.526	0.009	0.124
COV	0.385	0.617	1.107	0.944	0.371	1.030
Maximum	0.043	0.225	0.038	1.693	−0.006	0.466
Minimum	0.010	0.049	−0.003	0.075	−0.040	0.037
Range	0.033	0.176	0.041	1.618	0.034	0.429

Table 4. Impulse (IAP, IML, IL) of the force along the antero-posterior, medio-lateral, and long axis normalized by the body weight

	I_{AP} (s)		I_{ML} (s)		I_L (s)	
	Mean	COV	Mean	COV	Mean	COV
Step-to-step variability						
Subject 1	0.123	0.050	0.088	0.071	0.532	0.065
Subject 2	0.085	0.034	0.035	0.087	0.464	0.044
Subject 3	0.164	0.035	0.048	0.056	0.486	0.034
Subject 4	0.175	0.044	0.056	0.064	0.514	0.041
Subject 5	0.087	0.065	0.036	0.092	0.455	0.045
Subject 6	0.068	0.055	0.147	0.170	0.581	0.048
Subject 7	0.168	0.077	0.073	0.067	0.523	0.056
Subject 8	0.117	0.069	0.074	0.063	0.403	0.067
Subject 9	0.082	0.034	0.145	0.048	0.423	0.052
Subject 10	0.101	0.042	0.129	0.045	0.441	0.027
Subject 11	0.190	0.086	0.068	0.090	0.538	0.074
Subject 12	0.191	0.101	0.015	0.140	0.450	0.081
Subject-to-subject variability						
Mean	0.129	0.058	0.076	0.083	0.484	0.053
S.D.	0.046	0.022	0.043	0.038	0.054	0.016
COV	0.355	0.383	0.573	0.454	0.111	0.309
Maximum	0.191	0.101	0.147	0.170	0.581	0.081
Minimum	0.068	0.034	0.015	0.045	0.403	0.027
Range	0.123	0.067	0.132	0.125	0.178	0.054

Fig. 1. Overview of osseointegrated implant system including an implant and an abutment, as well as coordinate system.

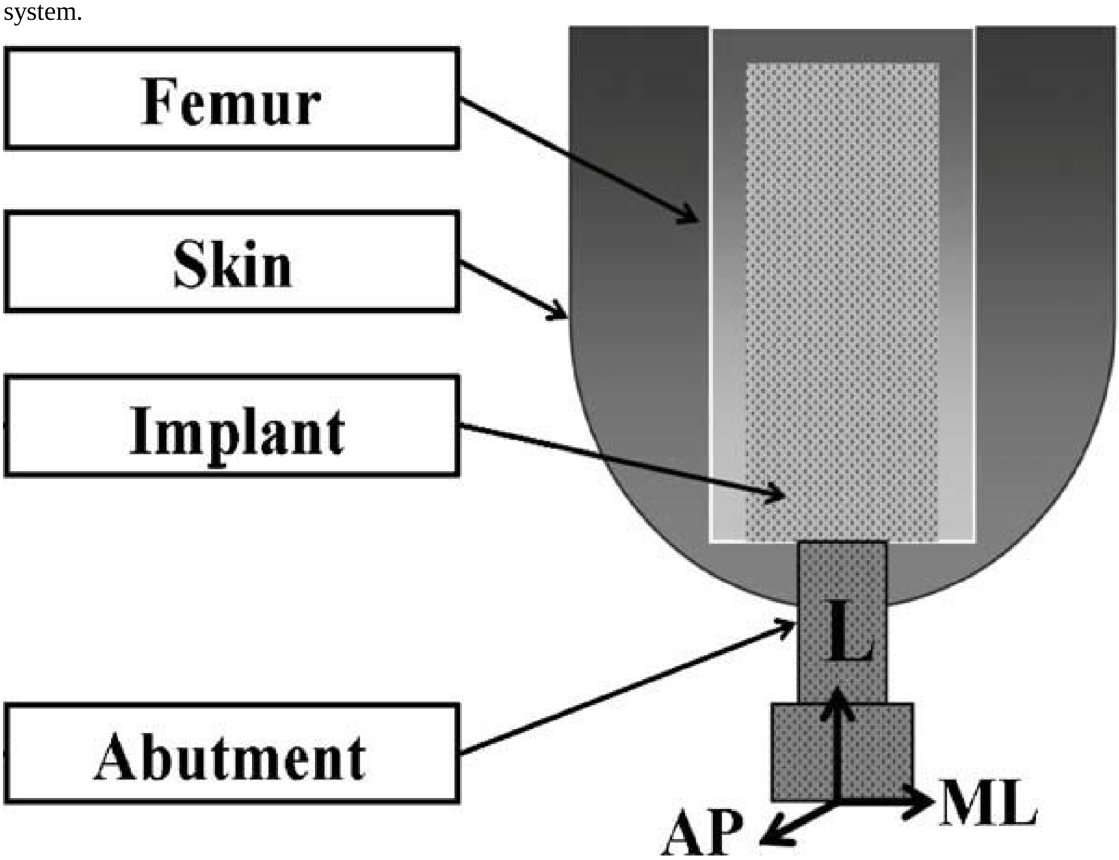

Fig. 2. Example of a typical prosthetic leg setup used to directly measure the forces and moments applied on the abutment of a transfemoral amputee (left: front view, right: side view). A commercial transducer (A) was mounted to specially designed plates (B) that were positioned between the adaptor (C) connected to the abutment (D) and the knee mechanism (F)

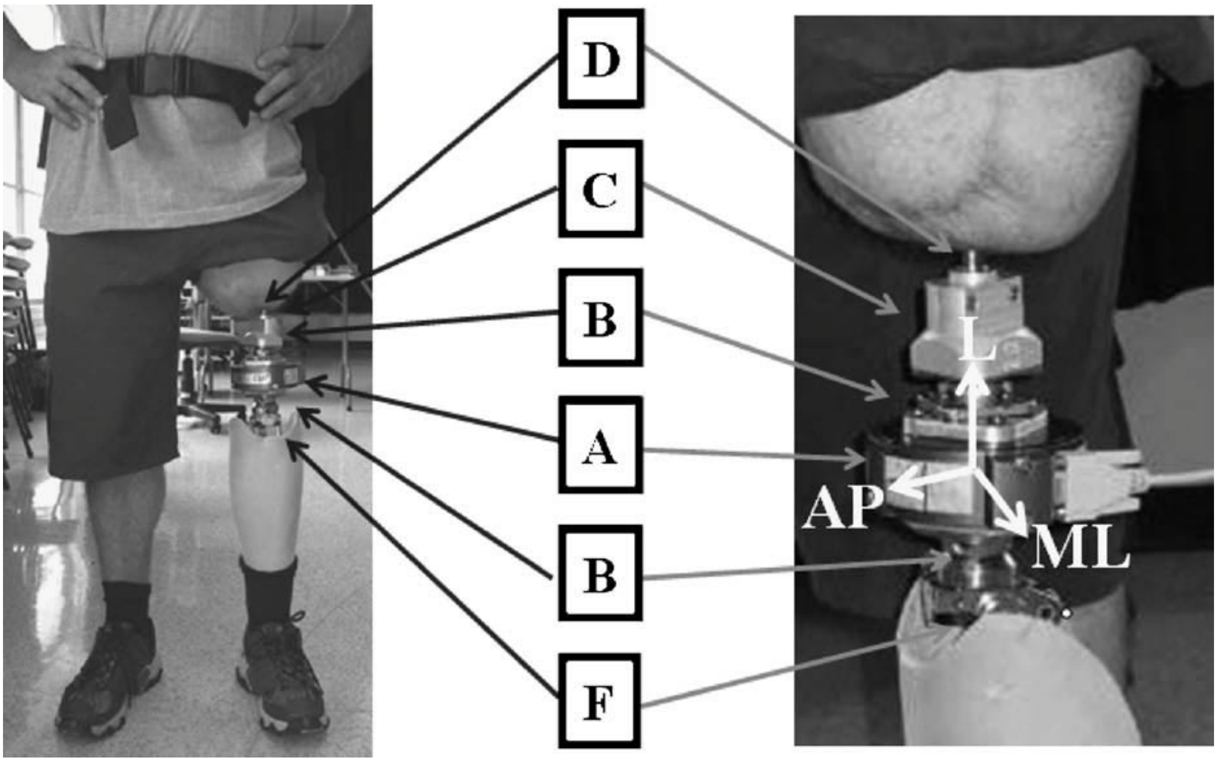

Fig. 3. Mean force expressed as a percentage of body weight of each subject applied on the abutment in (A) antero-posterior, (B) medio-lateral, and (C) long-axis directions for the 12 amputees versus percentage of gait cycle.

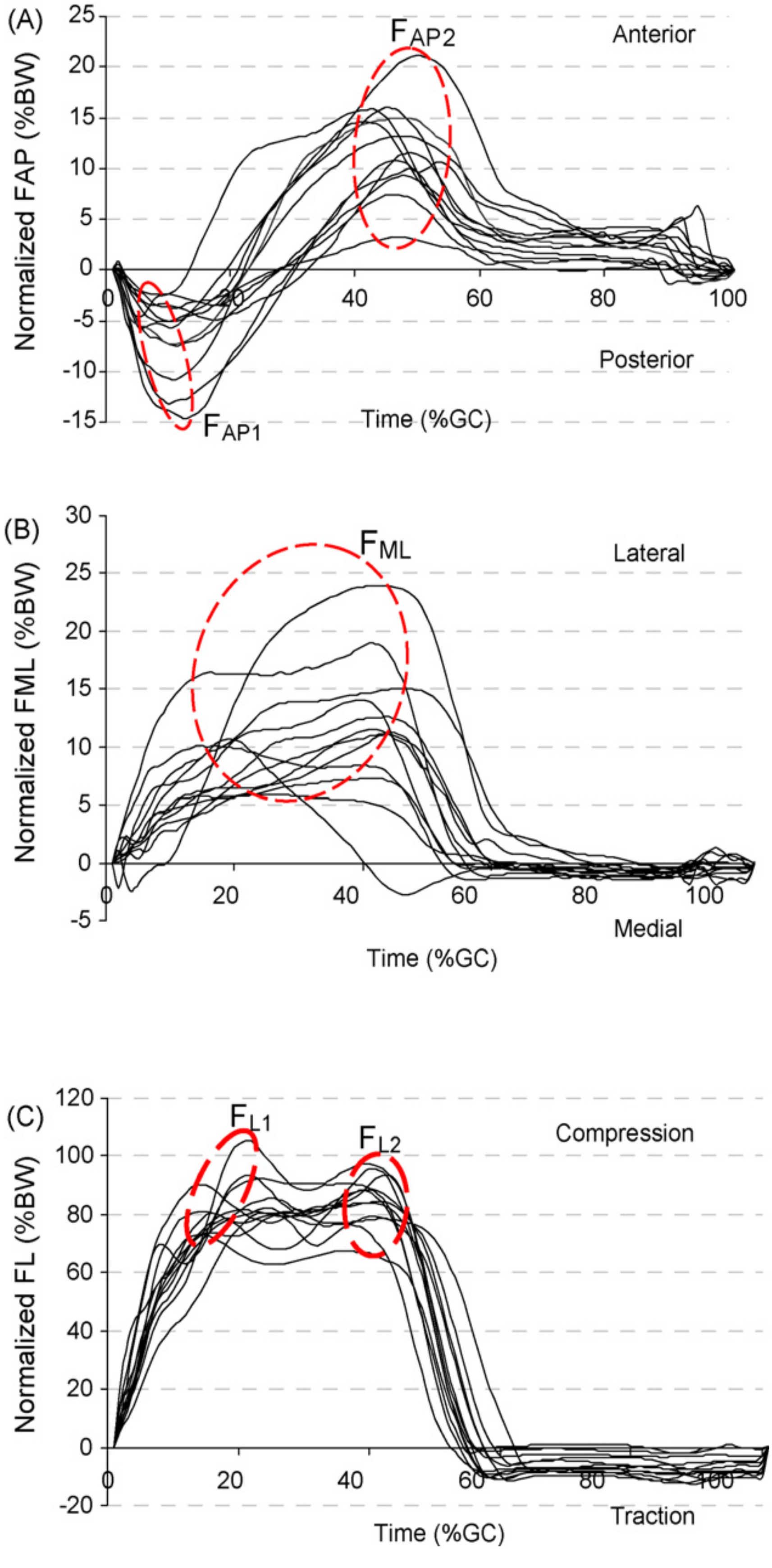

Fig. 4. Body weight normalized moment applied on the abutment about the (A) antero-posterior, (B) medio-lateral, and (C) long axis for the 12 amputees versus percentage of gait cycle.